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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,990	03/15/2004	Aaron B. Kantor	SURR.121	3053

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EXAMINER

CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/801,990

Applicant(s)

KANTOR ET AL.

Examiner

Jacob Cheu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1 and 44, 49-52, drawn to an isolated amino acid marker from Table 1-4, classified in class 436, subclass 86.
 - II. Claims 1 and 44, 49-52, drawn to an isolated polynucleotide marker from Table 1-8, classified in class 435, subclass 6.
 - III. Claims 2-15, drawn to a method of diagnosing rheumatoid arthritis by using the marker from Table 1-8, classified in class 435, subclass 7.1.
 - IV. Claims 16-29, drawn to a method of diagnosing rheumatoid arthritis by using a plurality of markers from Table 1-8, classified in class 436, subclass 86.
 - V. Claims 30-34, drawn to a method of monitoring the progression of rheumatoid arthritis in a subject, classified in class 436, subclass 173.
 - VI. Claims 35-37, drawn to a method of assessing the efficacy of a treatment for rheumatoid using marker from Table 1-4, classified in class 435, subclass 7.92.
 - VII. Claims 38-40, drawn to a method of assessing the efficacy of a treatment for rheumatoid using marker from Table 5-8, classified in class 436, subclass 149.
 - VIII. Claims 41-43, drawn to a method of treating rheumatoid arthritis by inhibiting expression of a gene from Table 1-4, classified in class 435, subclass 68.1.
 - IX. Claims 45-46, drawn to a method of determining the type, stage or severity of the rheumatoid arthritis in a subject using markers from Table 1-8, classified in class 435, subclass 967.
 - X. Claims 47-48, drawn to a method of risk of developing rheumatoid arthritis in a subject using markers from Table 1-8, classified in class 436, subclass 171.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions of group I

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and II direct to amino acid markers and polynucleotide markers, respectively. Both amino acid and DNA are patentably distinct with respect to its physical, chemical and biological functions.

3. Inventions I-II and III-X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the products from group I-II can be used in a materially different process, such as isolation and characterization.

4. Inventions III and IV-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the feature of determining one marker for diagnosing rheumatoid arthritis (RA) in group III, is not required by the claims of other groups. The feature of determining a plurality of markers for diagnosing RA in group IV, is not required by the claims of other groups. The feature of comparing two samples from the subject for determining the progression of RA in group V, is not required by the claims of other groups. The feature of determining markers in a subject from Table 1-4 for determining the efficacy of a treatment of RA in group VI, is not required by the claims of other groups. The feature of determining markers in a subject from Table 5-8 for determining the efficacy of a treatment of RA in group VII, is not required by the claims of other groups. The feature of inhibiting expression of a gene product from Table 1-4 for treatment of RA in group VIII, is not required by the claims of other groups. The feature of determining markers from Table 1-8 for determining the type, stage or severity of RA in a subject in group IX, is not required by the claims of other group. The feature of determining markers from Table 1-8 for determining the risk of developing RA in a subject in group X, is not required by the claims of other group.

5. If group I is elected, applicant is further required under 35 U.S.C. 121 to elect a specific marker from Table 1-4.

6. If group II is elected, applicant is further required under 35 U.S.C. 121 to elect a specific marker from Table 1-8.

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7. If group III is elected, applicant is further required under 35 U.S.C. 121 to elect a specific marker from Table 1-8.
8. If group IV is elected, applicant is further required under 35 U.S.C. 121 to elect a specific marker from Table 1-8.
9. If group V is elected, applicant is further required under 35 U.S.C. 121 to elect two specific markers from Table 1-8.
10. If group VI is elected, applicant is further required under 35 U.S.C. 121 to elect a specific marker from Table 1-4.
11. If group VII is elected, applicant is further required under 35 U.S.C. 121 to elect a specific marker from Table 5-8.
12. If group VIII is elected, applicant is further required under 35 U.S.C. 121 to elect a specific marker from Table 1-4.
13. If group IX is elected, applicant is further required under 35 U.S.C. 121 to elect a specific marker from Table 1-8.
14. If group X is elected, applicant is further required under 35 U.S.C. 121 to elect a specific marker from Table 1-8.
15. The reason for election of specific markers is because:

Each marker is patentably distinct with respect to its chemical, physical and biological characteristics. There is no core-structure sharing among each marker. Applicant is reminded that election each marker from group I-X is **NOT a SPECIES ELECTION** since each marker is patentably distinct.

16. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, the search required for one group is not required for the other, therefore restriction for examination purposes as indicated is proper.

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17. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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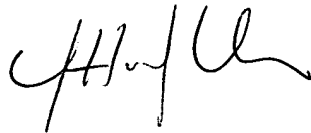
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jacob Cheu

Examiner

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May 25, 2006




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SUPERVISORY PATENT EXAMINER
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